47. (New) The method of claim 36, wherein the guanidine derivative is guanabenz acetate or a pharmaceutically acceptable derivative thereof and the pharmaceutically effective amount is about 0.25 mg/kg.

48. (New) The method of claim 36, wherein the guanidine derivative is an α - adrenergic agonist.

In view of the above amendments and following remarks, reconsideration and allowance of the application is hereby respectfully requested.

REMARKS

In the Amendment filed on June 19, 2002, and in response to the restriction requirement under 35 U.S.C. § 121, Group I (claims 1-19) were canceled without prejudice. Thus, claims 20-35 (Group II) are pending in the application for examination on the merits along with newly added claims 36-48.

Independent claim 20 has been amended consistent with the Examiner's suggestion during the interview to change the term "comprised" to "consisting

essentially" to overcome the 35 U.S.C. § 103(a) art rejection.

For the reasons set forth below, applicant has added new claims 36-48 in which independent claim 36 is directed to a method of inducing rapid onset and long lasting sedation and analgesia in a *standing equine* animal, comprising administering to the animal a pharmaceutically effective amount of a composition *comprised* of a guanidine derivative. New claim 36 is essentially the same as originally filed claim 20 with the additional limitations of dependent claims 27 and 28 as originally filed.

A "VERSION WITH MARKINGS MADE TO SHOW CHANGES" (pages 10-12) and an "AMENDED VERSION WITHOUT MARKINGS" (pages 13-15) of amended claim 20 and newly added claims 36-48 is being submitted concurrently herewith.

Rejection Under 35 U.S.C. § 103(a)

The Examiner's rejection of claims 1-19 under 35 U.S.C. § 103(a) was rendered moot in the instant application by the cancellation without prejudice of claims 1-19 in the Amendment dated June 19, 2002.

The rejection of claims 20-35 under 35 U.S.C. § 103(a) is believe to have been overcome by the amendment of independent claim 20 consistent with the Examiner's suggestion in the Interview Summary dated July 11, 2002.

Likewise newly added claims 36-48 are believed to be free of art and are believed to be in condition for allowance. None of the art of record teaches or suggests a method of inducing rapid onset and long lasting sedation and analgesia in a *standing equine* animal, comprising administering to the animal a pharmaceutically effective amount of a composition *comprised* of a guanidine derivative.

In particular, U.S. Patent No. 5,635,204 is directed to the use of a *required combination* of drugs to induce *general anesthesia* or a surgical stage of anesthesia in a recumbent individual. The specification of the '204 patent at column 2, lines 9-23 specifically recites the required combination of drugs for induction of *general anesthesia*, namely fentanyl or a fentanyl analog (line 12); an α_2-adrenergic agonist such as clonidine (lines 13-16); and an amnesia inducing drug such as ketammine (lines 17-19).

There is absolutely no teaching or suggestion anywhere in the '204 patent of a method of rapid induction of long lasting sedation and analgesia in a standing equine animal (*e.g.*, a horse) via administration of a single guanidine derivative as set forth in

new independent claim 36. As demonstrated in applicant's video, a single administration of a guanidine derivative produced profound sedation and analgesia and an effective means of a rapidly reversible *chemical restraint* for horses.

General or surgical anesthesia places an animal in recumbancy and increases the risk to the patient and, as set forth in the '204 patent, *requires* administration of additional drugs, namely narcotics and dissociative anesthetic agents such as fentanyl and ketamine respectively, which increase the risk of adverse reactions in the patient. The methods of newly added claims 36-48 do not require administration of any agent other than a guanidine derivative for induction of the desired sedation and analgesia *in a standing equine animal* and cannot be obvious in view of the teachings of the '204 patent.

Accordingly, in view of the amendment of claim 20 and the remarks set forth above withdrawal of the rejection of claims 20-35 under 35 U.S.C. § 103(a) is believed to be warranted and is earnestly solicited. Likewise, for the reasons set forth above, newly added claims 36-48 are also believed to be in condition for allowance.

Related Matters

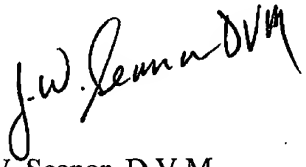
This amendment is being submitted by facsimile transmittal to (703) 308-4556.

And, as requested, a courtesy copy of this amendment is also being faxed to the Examiner at (703) 746-5317.

No additional fee is believed to be due, however, the Commissioner is hereby authorized to debit or credit deposit account number 11-0978 for any additional fees deemed to be due or issue a credit for any overpayment thereof. The Examiner is encouraged to contact the undersigned attorney directly if such contact will enhance the efficient prosecution of the application to issue.

Respectfully submitted,

KING AND SCHICKLI, PLLC



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I hereby certify that this correspondence is being transmitted by facsimile to: Assistant Commissioner for Patents, Washington, D.C. 20231, to telephone number **(703) 308-4556** on:

August 1, 2002
Date

J.W. Lemma Dr M
By

Docket No. 434-226 Patent

VERSION WITH MARKINGS MADE TO SHOW CHANGES

20. (Amended) A method of inducing rapid onset and long lasting sedation and analgesia in an animal, comprising administering to the animal a pharmaceutically effective amount of a composition consisting essentially ~~comprised~~ of a guanidine derivative.

36. (New) A method of inducing rapid onset and long lasting sedation and analgesia in a standing equine animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a guanidine derivative.

37. (New) The method of claim 36, wherein the guanidine derivative is selected from the group consisting of guanabenz, guanabenz acetate, guanoxabenz, clonidine, guanacline, guanadrel, guanazodine, guanethidine, guanfacine and guanochlor, guanoxan and chlonidine.

38. (New) The method of claim 36, wherein the guanadine derivative is guanabenz acetate or a pharmaceutically acceptable derivatives thereof.

39. (New) The method of claim 36, wherein the administration is oral.

40. (New) The method of claim 36, wherein the administration is intravenous.

41. (New) The method of claim 36, wherein the administration is intramuscular.

42. (New) The method of claim 36, further comprising the step of selectively reversing or controlling the level of analgesia and sedation in the animal comprising administering a pharmaceutically effective amount of α adrenergic antagonist to the animal.

43. (New) The method of claim 42 wherein the α adrenergic antagonist is selected from the group consisting of yohimbine, rauwolscine, idazoxan and atepamezole.

44. (New) The method of claim 36, wherein the pharmaceutically effective amount of the guanidine derivative is between about 0.05 mg/kg and about 0.50 mg/kg.

45. (New) The method of claim 36, wherein the pharmaceutically effective amount of the guanidine derivative is about 0.25 mg/kg.

46. (New) The method of claim 36, wherein the guanidine derivative is guanabenz acetate or a pharmaceutically acceptable derivative thereof and the pharmaceutically effective amount is between about 0.05 mg/kg and about 0.50 mg/kg.

47. (New) The method of claim 36, wherein the guanidine derivative is guanabenz acetate or a pharmaceutically acceptable derivative thereof and the pharmaceutically effective amount is about 0.25 mg/kg.

48. (New) The method of claim 36, wherein the guanidine derivative is an α - adrenergic agonist.